MAZIE SLATER KATZ & FREEMAN, LLC
COUNSELLORS AT LAW
103 Eisenhower Parkway
Roseland, NJ 07068
(973) 228-9898
Fax (973) 228-0303
www.mazieslater.com

David A. Mazie*
Adam M. Slater*°
Eric D. Katz*°
David M. Freeman
Beth G. Baldinger
Matthew R. Mendelsohn°

Karen G. Kelsen°
Cheryll A. Calderon
David M. Estes
Adam M. Epstein°
Michael R. Griffith°
Matthew Tonzola
Christopher J. Geddis

*Certified by the Supreme Court of New Jersey as a Civil Trial Attorney

°Member of N.J. & N.Y. Bars

January 14, 2020

VIA ECF
Honorable Joel Schneider
United States Magistrate Judge
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, New Jersey 08101

Re: IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION
Civil No. 19-2875 (RBK/JS)

Dear Judge Schneider:

Please accept this letter on behalf of the Plaintiffs addressing the issues to be discussed during the January 15, 2020 status conference.

1. **Expansion of the MDL**

The parties have begun discussions regarding the path forward with the expansion of the MDL to include claims involving Losartan and Irbesartan. Plaintiffs believe that the new claims can be efficiently absorbed into the existing structure of the MDL, while maintaining the momentum already established with regard to the Valsartan claims. In the short term one priority

is the entry of a direct filing order to encompass the new claims, which Plaintiffs request be entered as soon as possible.

2. **Downstream Defendant Discovery**

The parties are in the process of ongoing discussions which have been productive, and it is anticipated that agreement will be reached with the retailer and wholesaler/distributor defendants, on document requests and DFS's. In order to reach agreement on streamlined requests Plaintiffs reserve the right to supplement the requests as needed as discovery proceeds and potential trial issues become clear, and Defendants have agreed to this. To the extent that there are any disputed issues, these should be limited and can be resolved at the January 28, 2020 discovery hearing.

3. **Manufacturer Defendant Fact Sheets**

The manufacturer Defendants have indicated they do not believe that they should be required to complete a DFS. Plaintiffs of course disagree, as discussions and arguments regarding discovery have always been undertaken with the understanding of the parties and the Court that certain information with regard to the claims brought by named and individual plaintiffs (i.e. product ID/lot and batch ID, communications with specific treating doctors, etc.) would require information to be provided on a case specific basis through the DFS.

4. **Preservation of Recalled Product**

Plaintiffs were recently shocked when informed by Defendants that despite their litigation hold/preservation obligations, including but not limited to those imposed by this Court's initial case management order, some or all of the Defendants had been destroying recalled pills. The full extent of this potential spoliation issue is not yet known, and Plaintiffs request a complete accounting of all pills returned or held due to nitrosamine contamination (actual or potential), and

what has been done with those pills. This is critical for the Plaintiffs and the Court to assess the extent and merits of the issue. Plaintiffs also request entry of yet another Order reiterating the Defendants' obligation to preserve evidence including contaminated and potentially contaminated pills.

With respect to the arguments Defendants make in their Letter to the Court (D.E. 388), Defendants' arguments lack merit. First, Defendants purposefully misconstrue Plaintiffs' letter requesting that they preserve recalled product. Plaintiffs did not request production of the recalled and/or contaminated pills. Rather, at this juncture, Plaintiffs' simply reminded Defendants of their ongoing, and wholly independent, preservation duties. *See* Ex. A (October 25, 2019, Letter to Goldberg) ("Plaintiffs specifically request that Defendants preserve and do not destroy or otherwise dispose of….product, in compliance with Defendants' preservation obligations under CMO No. 1…and [the] Federal Rule[s]"). Remarkably, Defendants appear poised to argue that they are somehow only required to preserve evidence to the extent that it does not require "significant resources." D.E. 388 at 13. This position is unmoored from any order, and longstanding jurisprudence. Defendants' preservation obligations are affirmative in nature and arose at a time when Defendants knew the litigation was "pending or probable" and when Defendants could foresee "the harm or prejudice that would be caused to the party seeking the evidence if the evidence were to be discarded." *Hohider v. United Parcel Serv., Inc.*, 257 F.R.D. 80, 82 (W.D. Pa. 2009). Further, Defendants' preservation obligations are completely separate from, and independent of, Plaintiffs' obligations under the Federal Rules to ensure that discovery requests are proportionate. *See Al Otro Lado, Inc. v. Nielsen*, 328 F.R.D. 408, 418 (S.D. Cal. 2018) ("While plaintiffs are required to articulate defined requests for preservation and/or production, so

too must defendants take seriously their independent obligation to preserve information"). Additionally, as discussed below, it appears as though *some* Defendants affirmatively recognized that recalled product needed to be preserved, even before Plaintiffs sent a letter reminding all Defendants of their obligation. If it is not an unduly burdensome proposition for one Defendant to preserve product, then other Defendants cannot credibly argue that it is an unduly burdensome proposition for them to preserve product.

With respect to their hollow preemption argument, Defendants overreach when they claim that Plaintiffs are "dictat[ing] the handling of FDA-regulated drugs" and that Plaintiffs' preservation request "undermines the federal scheme." D.E. 338 at 11. Courts have routinely required stays of mandated governmental document destruction programs to cease destruction of potentially relevant documents, even in instances where the Federal Government is a non-party to the litigation. *See In re "Agent Orange" Prod. Liab. Litig.*, 506 F. Supp. 750 at 751 (E.D.N.Y. 1980). Defendants' argument as to primary jurisdiction is likewise unpersuasive. Defendants purposefully mischaracterize *Clark* when they argue that Judge Greenaway "considered this same issue." D.E. 311 at 12. Defendants fail to note that the Plaintiffs in *Clark* were not seeking an order from the Court requiring the Defendants to preserve the FDA device in the Defendant's exclusive possession once recalled. Rather, the *Clark* Plaintiffs were requesting that the Court essentially order the Defendants to **cease recalling the products from the market entirely.** *Clark v. Actavis Grp. hf*, 567 F. Supp. 2d 711, 718 (D.N.J. 2008 ("Specifically, Plaintiffs request that this Court order "Defendants to cease and desist all efforts inducing consumers to return [their remaining Digitek® tablets] to Defendants, rather than preserving the drug and packaging themselves; and ... to preserve all Digitek® tablets and[/]or other items returned by consumers as

part of the recall.") Plaintiffs' request in this case to Defendants to preserve recalled pills will in no way frustrate their continuing efforts to recall pills from the market.

Were this not enough, Defendants' argument as to primary jurisdiction is fatally undermined by their own conduct, and the FDA's own communications regarding the real world recall at issue in this case. It is worth noting that Defendants' obligation with respect to the recall only allows a manufacturer to destroy product upon receiving affirmative approval to destroy this product from the FDA. *See* MYLAN-MDL2875-00039113 ("The product will be in quarantine until approval by the FDA for destruction of the product") (emphasis added). Defendants are not in any way defying the FDA by not destroying pills. Indeed, Plaintiffs' preservation requests and the FDA's demands during the recall are aligned in the fact that the Defendants are not allowed to *sua sponte* destroy pills on their own. Additionally, the FDA is fully aware that certain manufacturers are keeping pills in quarantine (rather than destroying them) pursuant to litigation holds *in this case*. For example, one Defendant informed the FDA (no fewer than 7 times) that they had initiated a legal hold preventing them from destroying product. In addition, this Defendant appeared to have a phone call with the FDA regarding the destruction of pills *almost a month after* Plaintiffs' October 25, 2019 letter was served, demanding preservation of recalled pills, and the FDA appeared to raise no concerns over the non-destruction of contaminated pills.[1] Mylan also has indicated to the FDA that they will not be destroying pills. *See* MYLAN-MDL2875-00030975

[1] Because this Defendant designated these ministerial and presumptively public communications with the FDA as "confidential," Plaintiffs cannot more fully describe the contents of this Defendant's communications with the FDA regarding pill destruction and its legal hold without filing this letter under seal. Plaintiffs will be prepared to discuss this Defendant (and questions that these communications raise about whether some products may have been destroyed despite ongoing legal holds) more fully with the Court during the telephonic hearing.

("…we will not request destruction at this time…"). These documents demonstrably prove that Plaintiffs' preservation request is not frustrating the efforts of the FDA in administering the Valsartan recall.

Defendants were to produce (on an ongoing basis) correspondence with the FDA regarding the recall pursuant to the Core Discovery Order (D.E. 88). However, as discussed *infra* at No. 7, Plaintiffs have serious concerns about Defendants' compliance with this provision. As such, in light of the foregoing, Plaintiffs request the following specific information from each Defendant as it relates to the destruction of recalled pills:

- Status of the recall for each Defendant (i.e., is the recall still ongoing, or closed);
- Names and identities of any and all third parties used to keep and/or destroy recalled products;
    - Plaintiffs have identified the following third parties used by some Defendants in the recall efforts, but request all names of all unidentified third parties being used to destroy pills: Inmar (Teva, Aurobindo); Qualanex (Torrent, Hetero). Plaintiffs understand ZHP utilized a contract warehouse but have been unable to locate the name of the warehouse in any core discovery produced to date. Plaintiffs' cannot discern whether Mylan used a third-party to warehouse and/or quarantine product.
- The dates of any and all destructions;
- Copies of any and all destruction certifications and/or receipts, including the dates of those destructions, and the manner of destruction (i.e., incineration); and

- Correspondence from the FDA confirming approval of destruction of pills (no such correspondence appears in Core Discovery despite Defendants' continuing obligation to update core discovery pursuant to D.E. 88).

5. **Short Form Complaints Not Properly Filed**

The parties are conferring to identify the specifics of these issues and to contact the law firm(s) involved, and remedy the situation.

6. **Motions for Extensions of Time**

The parties are conferring to identify the specifics of these issues and to contact the law firm(s) involved, and remedy the situation.

7. **Status of Ongoing Core Discovery Productions**

Plaintiffs have serious concerns about several Defendants' compliance with the Core Discovery order (D.E.88). Pursuant to the Core Discovery Order, Defendants are under a continuing and ongoing obligation to produce all communications it sends or receives from the FDA regarding the ARB recall, the investigation into the cause of the alleged contamination, and the efforts to contain, remove or detect the contamination **no later than seven (7) days after the date of the correspondence**. *See* D.E. 88 (emphasis added). Based on obvious gaps in the productions from multiple defendants it is quite likely that one or more defendants are in violation of the Court's Order.

Part of this concern stems from the fact that Defendants (at the very least ZHP, and possibly Hetero Labs) appear to be outsourcing their communications with the FDA regarding the recall to third-parties (including "consultants" and law firms) who are not employed by the company.

On October 28, 2019, Plaintiffs raised their concerns with respect to two different designated agents appointed by Defendant ZHP. One such consultant is a former FDA inspector who ZHP appointed as a US Agent in December of 2018 to communicate with the FDA. *See* PRINSTON0073199.[2] Another third party who has been communicating with the FDA as an agent for ZHP is Duane Morris partner Frederick Ball. *See* PRINSTON00078994. Despite sending this letter to Defendant ZHP almost 3 months ago, and hollow promises that they would "look into the issue," ZHP has not provided any further production of any such communications between these third parties and the FDA or requested information about in person meetings, and/or telephonic communications with the FDA. ZHP has also not produced any communication between itself and the FDA beyond one letter written in September of 2019. *See* PRINSTON0079006. Given the severity of the warning letter, it seems likely that there has been additional correspondence between ZHP and the FDA from September of 2019 to present.

On December 27, 2019, Teva made a supplemental production of 428 documents, which consisted of communications with the FDA regarding the recall as it related to pill destruction. The lion's share of these documents are dated prior to Teva's production of Core Discovery documents made during the summer of 2019, and should have been produced months ago, but were not. Additionally, in this "supplemental" production, Teva appears to have omitted production of the referenced December 12, 2019, email from the FDA which memorialized the communications made between Teva and the FDA on November 21, 2019.

[2] Because Defendant ZHP designated these presumptively public communications with the FDA as "Restricted Confidential Information," Plaintiffs cannot further describe the nature of Mr. Gu's communications with the FDA, or the troubling manner in which Mr. Gu appeared to be communicating with the FDA. Plaintiffs will be prepared to more fully discuss these communications on the telephonic hearing.

The foregoing illustrations demonstrate likely non-compliance with the Court's Order, and Plaintiffs request definitive relief.

8. Status of Defendants' Compliance with Order Regarding Testing

In November 2019 (D.E. 303), the Court ordered the Defendants to provide lists of all testing performed so that Plaintiffs could be sure that no important tests are overlooked. Defendants inexplicably continue to refuse to comply, pointing to their identification of bates numbers of documents referencing testing as if that satisfies the clear obligation under the Order. Plaintiffs do not believe that it should be necessary to continue to discuss this issue or justify the basis for an Order already entered by the Court.

9. Status of Motion to Dismiss Filed by Legacy in Roddey v. Camber, et al.

A motion to dismiss based on asserted lack of personal jurisdiction, based on the Bristol Myers decision, was filed in this newly added Losartan related case was filed previously. This motion, which is puzzling since Legacy apparently obtained its contaminated Valsartan pills from distributors in New Jersey, requires opposition to be filed on January 25, 2020. Plaintiffs request that the motion be carried without a specific return date, and not be heard at this stage of the litigation. In the event the Court is inclined to hear the motion in the nearer term, Plaintiffs request jurisdictional discovery, including potential depositions, and the opportunity for Plaintiffs' leadership to participate in the opposition to this motion, perhaps through a separate brief, due to the importance of this issue to the litigation as a whole.

Respectfully,

ADAM M. SLATER